

## **Pakaian dan kain bedah – Persyaratan dan metode uji – Bagian 2: Baju ruang steril**

### **Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits**

(EN 13795-2:2019, IDT, Eng)

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## Prakata

Standar Nasional Indonesia (SNI) EN 13795-2:2019, dengan judul *Pakaian dan kain bedah – Persyaratan dan metode uji – Bagian 2: Baju ruang steril (EN 13795-2:2019, IDT, Eng)*, merupakan hasil adopsi identik dari standar EN 13795-2:2019 *Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits*, dengan metode republikasi *reprint*, yang ditetapkan oleh BSN pada tahun 2020.

Standar ini disusun oleh Komite Teknis 13-09 Biosafety and Biosecurity dengan Badan Standardisasi Nasional (BSN) sebagai sekretariat Komite Teknis. Standar ini telah dibahas dalam rapat-rapat teknis, dan terakhir disepakati dalam rapat konsensus di Jakarta pada tanggal 17 April 2020 yang dihadiri oleh para pemangku kepentingan (*stakeholder*) terkait, yaitu perwakilan dari produsen, konsumen, pakar dan pemerintah, serta perwakilan dari lembaga pengujian, asosiasi, perguruan tinggi, pakar serta instansi terkait.

Standar ini telah melalui tahap jajak pendapat pada tanggal 11 Mei 2020 sampai dengan 30 Mei 2020 dengan hasil akhir disetujui menjadi SNI.

Dalam standar ini digunakan kosa kata yang mempunyai maksud tertentu, yaitu:

- “harus” yang artinya disyaratkan.
- “sebaiknya” yang artinya direkomendasikan.

Perlu diperhatikan bahwa kemungkinan beberapa unsur dari dokumen standar ini dapat berupa hak paten. Badan Standardisasi Nasional tidak bertanggungjawab untuk pengidentifikasian salah satu atau seluruh hak paten yang ada.



## Pendahuluan

Clean air suits are used to minimize the spread of infective agents to patients' surgical sites and equipment, through prevention of dispersal of bacteria-carrying skin scales from the operating room staff, thereby helping to prevent post-operative surgical site infections.

The performance required of working clothes for clinical staff varies with, for example, the type and duration of the procedure, and the susceptibility of the patient to infection. In infection-prone invasive operations, a clean air suit can contribute to reduction of infection risks, in conjunction with ventilation and correct working methods.

This document is intended to assist the communication between manufacturers and third parties with regard to material or product characteristics and performance requirements.

Therefore, Annex B provides comprehensive information on characteristics, measurement of performance and performance requirements. Annex C clarifies that this document does not include environmental provisions. Annex D explains the concept of performance levels and provides guidance to users for selecting products. Annex E gives information on the impact of the design of clean air suits and the source strength concept as an evaluation means for the impact of the entire clothing (including clean air suits) on particle release.

This document focuses on Essential Requirements arising from the Medical Device Directive 93/42/EEC, which are applicable to clean air suits. The requirements and guidance in this document are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of this document to ensure the same level of safety from single-use and reusable clean air suits throughout their useful life.



## **Pakaian dan kain bedah – Persyaratan dan metode uji – Bagian 2: Baju ruang steril**

### **1 Scope**

This document specifies information to be supplied to users and third party verifiers in addition to the usual labelling of medical devices (see EN 1041 and EN ISO 15223-1), concerning manufacturing and processing requirements.

This document gives information on the characteristics of single-use and reusable clean air suits used as medical devices for clinical staff, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures.

This document specifies test methods for evaluating the identified characteristics of clean air suits and sets performance requirements for these products.

### **2 Normative reference**

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 29073-3:1992, *Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation*

EN ISO 139:2005<sup>1</sup>, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005 + Amd. 1:2011)*

EN ISO 9073-10:2004, *Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)*

EN ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)*

EN ISO 11737-1:2018, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

EN ISO 13938-1:1999, *Textiles - Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

EN ISO 22612:2005, *Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration (ISO 22612:2005)*

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<sup>1</sup> Impacted by EN ISO 139:2005+A1:2011



### 3 Term and definition

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

#### 3.1

##### colony forming unit

##### CFU

unit by which the culturable number of microorganisms is expressed

**NOTE 1** to entry: The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

#### 3.2

##### clean air suit

suit, used as working garment, intended and shown to minimize contamination of the operating room air from skin scales originating on the skin of persons wearing it

**NOTE 1** to entry: A scrub suit is a working garment for operating room staff that does not need to meet the requirements for a clean air suit. The scrub suit is not primarily intended to prevent airborne dispersal from staff, and can be designed and processed as the manufacturer thinks fit.

**NOTE 2** to entry: A clean air suit consists of a coverall, or a blouse and trousers.

#### 3.3

##### cleanliness

freedom from unwanted foreign matter

**NOTE 1** to entry: Such matter can be microorganisms, organic residues or particulate matter.

##### 3.3.1

##### cleanliness — microbial

freedom from population of viable micro-organisms on a product and/or a package

**NOTE 1** to entry: In practical use, microbial cleanliness is often referred to as 'bioburden'.

#### 3.4

##### infective agent

microorganism that has been shown to cause wound infections or that might cause infection in a member of the surgical team or the patient

#### 3.5

##### manufacturer

natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

**NOTE 1** to entry: For more details refer to the Medical Device Directive 93/42/EEC.



### 3.6

#### **particle release**

release of fibre fragments and other particles during mechanical stress simulating handling and use

### 3.7

#### **performance level**

discrete standard defined to classify products according to the performance requirements of this document

**NOTE 1** to entry: With the introduction of two performance levels this document acknowledges the fact that products are challenged to differing extents during surgical procedures, dependent upon the microbial cleanliness of the operating room required for the procedure.

#### 3.7.1

##### **standard performance**

classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

#### 3.7.2

##### **high performance**

classification addressing elevated performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

**NOTE 1** to entry: Examples of surgical procedures where high performance level might be considered are infection prone clean surgical procedures where air counts in the operating room of  $\leq 10$  CFU/m<sup>3</sup> are required.

### 3.8

#### **processor**

natural or legal person who processes products so that their performance complies with the requirements of this document

**NOTE 1** to entry: A processor who places a product on the market is a manufacturer in the sense of this document.

**NOTE 2** to entry: A processor of reusable products is often referred to as a 'reprocessor' and processing reusable products is often referred to as 'reprocessing' (as e.g. in Medical Device Directive 93/42/EEC). References in EN 13795-1 and this document to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

### 3.9

#### **product**

clean air suit

### 3.10

#### **resistance to microbial penetration**

ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

#### 3.10.1

##### **dry penetration**

effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition



**3.11****reusable product**

product intended by the manufacturer to be reprocessed and reused

**3.12****single-use product**

product intended to be used once only for a single patient

**3.13****source strength**

average number of bacteria-carrying particles (CFU) emitted per second from a person wearing a specified garment during a certain activity in a specified environment

**3.14****surgical procedure**

surgical intervention performed by a surgical team

**3.14.1****invasive surgical procedure**

surgical procedure penetrating skin or mucosa

**4 Performance requirements**

To comply with this document, products shall meet all the requirements specified in this document including Table 1, when tested according to Annex A of this document throughout their useful life.

The biocompatibility of the product has to be evaluated and approved for acceptable risk in accordance with EN ISO 10993-1.

For general information on testing and details on the test methods given in this clause including Table 1 and their application for the purpose of this document, see Annex A.

**NOTE** Information on characteristics, which cannot be properly evaluated or which are not regarded normative (as e.g. 'comfort') is given in Annexes B, D and E.

**Table 1 — Characteristics to be evaluated and performance requirements for clean air suits**

Characteristic	Test method (for normative reference see clause 2)	Unit	Requirement	
			Standard performance	High performance
Microbial penetration - Dry	EN ISO 22612	CFU	$\leq 100^a$	$\leq 50^a$
Cleanliness microbial/Bioburden	EN ISO 11737-1	CFU/ 100 cm <sup>2</sup>	$\leq 100$	$\leq 100$
Particle release	EN ISO 9073-10	Log <sub>10</sub> (lint count)	$\leq 4,0$	$\leq 4,0$
Bursting strenght-Dry	EN ISO 13938-1	kPa	$\geq 40$	$\geq 40$
Tensile strenght - Dry	EN 29073-3	N	$\geq 20$	$\geq 20$
<sup>a</sup> Test conditions :challege concentration 108 CFU/g talcum and 30 min vibration time				



The test methods given in Table 1 are materials tests. In order to manufacture a functioning clean air suit, design shall also be considered. When the material of the clean air suit is tight, bacteria are dispersed through the openings for head, arms and feet. Arm and feet openings shall therefore be closed. A barrier hood should be worn, tucked into the gap at the neckline (see Annex E, E.1). If the clean air suit consists of blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting waist.

## **5 Manufacturing and processing requirements and documentation**

**5.1** The manufacturer and processor shall document that the requirements of this document are met and that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices.

**5.2** The manufacturer/processor shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements throughout product realization, including development, design, manufacture, testing, packaging, labelling, distribution and, for reusable products, processing and life-cycle control.

Inputs for product realization shall include the outputs from risk management.

A quality system such as EN ISO 13485 is recommended, in case of processing of reusable products applied in accordance with EN 14065

For testing processes, quantitative physical, chemical and/or biological tests are preferred.

**5.3** A clinical evaluation for clean air suits shall be carried out and shall consider the performance of the clothing system to establish fitness for purpose. The evaluation shall include the critical review of the applicable clinical literature and the results of post market surveillance and vigilance.

## **6 Information to be supplied with the product**

### **6.1 Information to be supplied to the user**

**6.1.1** The following information shall be supplied on request:

- a) the identity or information on the test methods used;
- b) the results of testing and test conditions for the characteristics given in Clause 4.

**6.1.2** The manufacturer shall inform the user of residual risks due to any shortcomings of the protection measures adopted.

**6.1.3** The manufacturer shall provide sufficient information about intended use of the product or product system when conducting a surgical procedure. This shall include information on the performance level of the product.

### **6.2 Information to be supplied to the processor**

For reusable products the manufacturer shall obtain information to be supplied to the processor on the number of reuses based on standardized processes, together with information on



measures for maintaining the technical and functional safety of the medical device and packaging.

**NOTE** EN ISO 15797, though dealing with workwear and personal protective equipment (PPE), can be useful in developing standardized methods for reusable surgical textiles since it contains information on the principles and equipment for simulated industrial laundering.

## **Annex A** **(normative)** **Testing**

### **A.1 General**

**A.1.1** Testing for evaluation of the performance of products shall be done according to the test methods specified in A.2. All test results and test conditions shall be recorded and retained.

**A.1.2** Testing shall be performed on the finished product. Testing shall include potential weak spots.

**NOTE 1** Performance requirements can vary in relation to the risk of transfer of infective agents to or from the wound and the sterile field, and in relation to the ventilation flow of the room.

**NOTE 2** To ensure product performance, combinations of materials or products in systems can be used.

**A.1.3** During manufacture and processing, testing shall be conducted according to the requirements of the manufacturer's and processor's quality system.

**A.1.4** Alternative test methods for monitoring may be used provided that they are validated and address the same characteristic and that the results have been shown to correlate with the test methods given in this document.

**A.1.5** Where the test methods of this document do not specify the atmosphere for pre-conditioning, conditioning and testing, the specifications of EN ISO 139 shall be applied. Prior to testing, the samples shall be conditioned in the relaxed state.

### **A.2 Test methods and conformance**

#### **A.2.1 Test method for evaluation of cleanliness microbial/bioburden**

For evaluation of cleanliness — microbial, the product shall be tested according to EN ISO 11737-1.

**NOTE** EN ISO 11737-1 does not provide a fixed test method but specifies requirements for test methods and test mechanisms. The requirements of EN ISO 11737-1 are such that different test methods developed in accordance with it provide comparable results.

Five specimens shall be tested. The results shall be expressed as CFU/100 cm<sup>2</sup>. Report the individual results and determine Md and Uq (see A.3). Uq shall be equal to or less than the performance requirements in Table 1.

#### **A.2.2 Test method for evaluation of particle release**

For evaluation of particle release, the product shall be tested according to EN ISO 9073-10.

**NOTE 1** EN ISO 9073-10 allows for the test method to be conducted in a laminar flow hood. It is important to validate that laminar flow is occurring if equipment required for the test is located in the hood.



As specified in EN ISO 9073-10, ten specimens, five for each side of the material, shall be tested. The result of the test, i.e. the coefficient of linting, shall be calculated for particles in the size range 3  $\mu\text{m}$  to 25  $\mu\text{m}$  and reported as  $\log_{10}$  of the count value. Report the individual results and determine  $M_d$  and  $U_q$  (see A.3).  $U_q$  shall be equal to or less than the performance requirements in Table 1.

**NOTE 2** Particles of this size range are considered to be capable of carrying microorganisms.

### **A.2.3 Test method for evaluation of bursting strength in dry state**

For evaluation of bursting strength, the product shall be tested according to EN ISO 13938-1. The size of the test area shall be 10  $\text{cm}^2$  (35,7 mm diameter).

The test conditions should be specified in the test report.

If there are differences in the test results of both sides of material, both sides should be tested and the results should be recorded.

Five specimens shall be tested. The pressure needed to break or compromise the barrier of the sample shall be reported. Report the individual results and determine  $M_d$  and  $L_q$  (see A.3).  $L_q$  shall be equal to or greater than the performance requirements in Table 1.

### **A.2.4 Test method for evaluation of tensile strength in dry state**

For evaluation of tensile strength, the product shall be tested according to EN 29073-3 in the dry states both in longitudinal and in lateral directions.

Five specimens shall be tested for each direction. The maximum force measured shall be reported. Report the individual results and determine  $M_d$  and  $L_q$  (see A.3).  $L_q$  shall be equal to or greater than the performance requirements in Table 1.

### **A.2.5 Test method for evaluation of dry microbial penetration**

For evaluation of dry microbial penetration, the product shall be tested according to EN ISO 22612.

If both sides of the material to be tested are different, the side intended to cover the contamination source during use as stated by the manufacturer shall be exposed to the contamination source.

**NOTE** The side intended to cover the contamination source during medical use is, e.g. the inner side of a clean air suit.

If the product has an antimicrobial treatment, it shall be mentioned in the test report since it can influence the results.

Ten specimens shall be tested. Report the individual results and determine  $M_d$  and  $L_q$  (see A.3).  $L_q$  shall be equal to or greater than the performance requirement in Table 1.

### **A.2.6 Test method for evaluation of biocompatibility**

The manufacturer shall complete the evaluation of the clean air suit according to EN ISO 10993-1:2009 and report the results of the evaluation.



### A.3 Treatment of results

In order to determine whether a sample conforms to the performance requirements of this document, it is necessary to convert the replicate results from a test into an acceptance value (or test statistic). The median ( $M_d$ ) was the chosen value (see Annex B), together with one of two test statistics a) the lower quartile value ( $L_q$ ) for minimum performance ( $PR_{min}$ ) and b) the upper quartile ( $U_q$ ) for maximum performance ( $PR_{max}$ ).

For conformance of the product the following values can be determined:

- $L_q \geq PR_{min}$  (see Table 1);
- $U_q \leq PR_{max}$  (see Table 1); and
- $M_d$ ,  $L_q$  and  $U_q$  (or any percentile value)

by using the following general method.

To calculate the  $k^{th}$  percentile (where  $k$  is 25 for identifying the lower quartile number and 75 for identifying the upper quartile value):

1. Order all the values in the data set from the smallest to largest;
2. Multiply  $k$  percent by the total number of values,  $n$ . This product is called the index;
3. If the index obtained in step 2 is not a whole number, round it up to the nearest whole number and go to step 4a. If the index obtained in step 2 is a whole number, go to step 4b;
- 4a. Count the values in your data set from left to right (from the smallest to the largest value) until you reach the number indicated by step 3. The corresponding value in the data set is the  $k^{th}$  percentile;
- 4b. Count the values in your data set from left to right until you reach the number indicated by step 2. The  $k^{th}$  percentile is the average of that corresponding value in the data set and the value that directly follows it.



## **Annex B** (informative) **Rationales**

### **B.1 General**

This annex provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this document necessitated by those developments.

The first task undertaken by CEN/TC 205/WG 14 in its early days was deciding on the key product characteristics which needed to be assessed. After much consideration four categories emerged, namely barrier properties, strength properties relevant to maintaining barrier properties, particle release and bioburden level. Most of the performance limits in this document are based on expert consensus.

In the operating room, several measures are taken to prevent deep post-operative wound infection. In clean operations, the skins of the patient or of other persons present in the operating room are the main sources of infection. Antimicrobial prophylaxis is often administered to kill or inhibit bacteria from infecting the wound, but with increasing risks of antimicrobial resistance can fail. Airborne contamination of the sterile field shall therefore be reduced to a minimum [14].

A level of  $\leq 10$  CFU/m<sup>3</sup> is generally accepted as a definition for ultra-clean air in operating rooms intended for infection-prone clean surgery [15]. This can be achieved through a combination of ventilations, clothing and restriction of movement in the operating room (see also Figure E.2).

### **B.2 Cleanliness – microbial**

The test for microbial cleanliness is intended to estimate the numbers of viable organisms on the products. This is frequently referred to as the 'bioburden', which manufacturers routinely measure.

In a bioburden (cleanliness) test, the presence of microorganisms is expected, and the test is designed to quantify the amount of microorganisms present (for example, through rinsing, filtering and counting).

The cleanliness limit of 100 CFU (Table 1) is based on what is routinely achievable at present, both for single-use and reusable clean air suits as finished products. For re-usable clean air suits, it requires a controlled laundry process. A controlled handling procedure is mandatory (e.g. one-product packaging) to reduce contamination during transport and storage.

### **B.3 Particle release**

This method is designed to measure the release of particles from the device.

Particle release is a concern during surgery as foreign body contamination can cause an increased frequency of postoperative complications such as keloids, wound dehiscence, incisional hernias, chronic abscesses, intestinal obstruction and, in some circumstances, even



death [16], [17]. Fibres from gowns and drapes which have been deposited in wounds have been shown to cause post-operative granulomas [18], [19]. Blood clots around fibres can cause emboli, obstructing vital blood vessels [20].

Fibres can also reduce the ability of tissue to resist infection, due to impaired function of the blood and tissue macrophage systems [21], [22].

As well as having a direct effect clinically, an indirect effect is observed, whereby fibres and particles released from operating room materials can deposit on surfaces in the operating room, providing a potential vector for microorganisms to be transported into wounds and cavities [23]. See section on "Resistance to microbial penetration" for a discussion on contamination versus infection.

The particulate size range of 3  $\mu\text{m}$  to 25  $\mu\text{m}$  has been chosen based on the opinion that particles smaller than 3  $\mu\text{m}$  are too small to carry microorganisms, and particles larger than 25  $\mu\text{m}$  are too large to remain airborne because of gravity. This is supported in work published by Noble in 1963 who found that "*Organisms associated with human disease or carriage were usually found on particles in the range 4  $\mu\text{m}$  to 20  $\mu\text{m}$  equivalent diameter*" [24].

#### **B.4 Bursting strength – dry**

This test is designed to assess the device's ability to withstand pressure over, for example, a clinician's elbow or hip and to ensure its barrier properties are not prejudiced by mechanical failure.

Materials with more than one layer can show several break points when tested for bursting strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the pressure needed to break or compromise the barrier of the sample.

The limit (see Table 1) is based on manufacturer's experience of products deemed to be clinically suitable in the market place.

#### **B.5 Tensile strength – dry**

The 'tensile strength' of a material is the maximum stress, generated by pulling or stretching the material that a material can withstand before failing.

The test is designed to assess whether the basic strength of the device material is sufficient to ensure its barrier properties are not prejudiced. It is a standard textile material test.

Materials with more than one layer can show several break points when tested for tensile strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the force needed to break or compromise the barrier of the sample.

The limit (see Table 1) is based on manufacturer's experience of products deemed to be clinically suitable in the market place.

Table 1 has limits for the material only in the dry state, as the clean air suit is expected to be protected by a gown or apron if exposed to wet conditions during use.



## B.6 Resistance to microbial penetration – dry

Dry bacterial penetration EN ISO 22612 is a test method that was designed to simulate the penetration of bacteria-carrying skin scales through fabrics.

This test provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.

Whilst the relationship between contamination and infection is complex - contamination of the surgical field does not necessarily lead to infection - it is generally agreed that healthcare facilities should consider methods to reduce levels of airborne particles carrying bacteria in operating rooms [25].

The skin is the most important source of airborne contamination in the operating room. A person releases approximately  $10^4$  skin particles per minute when walking and approximately 10 % of these carry bacteria. Activity and friction against the skin, e.g. from clothing, increase the dispersal. Bacteria carrying skin scales are dispersed from the human body surface mainly from the lower part of the torso.

Normal shedding of human skin cells (keratinocytes) produces individual cells which are approximately 25-30  $\mu\text{m}$  in diameter (when hydrated) [26]. Whyte and Bailey [27] noted that bacterial-carrying skin scales are on average about 20  $\mu\text{m}$  in size, whilst Mackintosh and colleagues [28] showed that dispersed skin fragments had a wide size range extending below 5  $\mu\text{m}$  for the minimum projected diameter (MPD), with a median MPD about 20  $\mu\text{m}$ , and with 7 % to 10 % less than 10  $\mu\text{m}$ . When skin scales pass through relatively impermeable clothing, they can also become fragmented, with the result that more than 50 % of the bacteria-carrying particles can be less than 5  $\mu\text{m}$ .

The skin scales behave aerodynamically as particles of unit density and size approximately 10  $\mu\text{m}$ . These particles are distributed in the operating room with air currents and settle on exposed surfaces, thereby contaminating the sterile field and causing infection of the surgical site.

For microorganisms to penetrate the material in the dry state, they need to be carried on a physical particle, for example, skin scales. In this test, the physical particles are composed of talc, where 95 % of the particles shall be  $\leq 15 \mu\text{m}$ . The referenced talc (Finntalc M15) has a median particle size of 4,5  $\mu\text{m}$ , a maximum size of approximately 17  $\mu\text{m}$ , and approximately 18 % of the particles are  $\leq 2 \mu\text{m}$ .

During the dry penetration test, the talcum particles are sifted through the material to be tested, and spore-forming bacteria are used as marker organisms. The test is intended to measure penetration of dust, e.g. skin scales through clothes, and has been shown to correlate well to airborne dispersal of bacteria.

The size range in the test talc covers the range of skin fragments found in practice down to particle sizes smaller than we would expect from skin fragmentation.

Penetration in this test method is influenced by the physical properties of the materials e.g. pore size and tortuosity factor.

The limit of  $\leq 100$  CFU (Table 1) is based on results of materials used for the manufacturing of clean air suits in clinical use today, both reusable and single-use.



Dry penetration is intended to examine the ability of a material to prevent airborne transmission. The test is particularly relevant for the clean air suit, which is intended to prevent airborne transmission when made from a tight material and adequately designed.

## **B.7 Labelling**

Labelling requirements are adequately covered in Section 13 of Annex I (Essential Requirements) of the Medical Device Directive.

## **B.8 Treatment of results**

The median,  $M_d$ , was chosen as the preferred statistic to the mean because of the small sample size and its greater robustness to the influence of outliers. Consequently, 25th and 75th percentiles ( $L_q$  and  $U_q$  respectively) were chosen as the test statistics for assessing compliance against the performance requirements in Table 1. More simply, for  $PR_{min}$ , for five replicates the highest four shall pass and for 10 replicates the highest eight shall pass. The method for determining  $L_q$  and  $U_q$  in A.3 gives the statistical justification for this.

It was recognized that manufacturers and processors may wish to use means and standard deviations for quality assurance purposes, especially where more data would be generated leading to better estimates of population statistics and the more reliable setting of processing conditions.

## **B.9 Flammability**

Though clean air suits do not provide ignition sources or oxidizer they might serve as fuel, when a fire breaks out. Manufactures are required to supply information regarding fire risks in relation to the use of their products. This document does not specify further essential requirements of Directive 93/42/EEC on Medical Devices or basic health and safety requirements of the Directive 89/686/EEC on Personal Protective Equipment regarding flammability of clean air suits.

## **B.10 Electrostatic discharge**

CEN/TC 205/WG 14 discussed whether specific tests for Electrostatic Discharge (ESD) were necessary in this document.

After taking advice from clinicians, hospital engineers, experts in electromedical equipment and electrostatic engineers, WG 14 note the following:

a) There are three potential risks from ESD:

ESD damage to equipment;

ESD ignition of flammable anaesthetic agents;

ESD ignition of flammable vapours (specifically alcohols).

b) The electrostatic immunity requirement according to IEC 60601-1-2:2014 is 15 kV. EN 61000-4-2:2009 has a useful graph in informative Annex A showing that synthetic fabrics can generate a maximum electrostatic voltage of 13 kV in rooms without humidity control (down to 15 %RH). Therefore the medical electrical equipment comply to the latest version of EN 60601-1-2 should be adequately protected from ESD.



- c) Traditional risks associated with flammable anaesthetic agents no longer exist in hospitals as these agents have all been replaced with safer alternatives.
- d) Use of flammable liquids in theatres is controlled, as diathermy would not be viable if there were a risk from sparks. Diathermy is a much greater risk than ESD.

Nowadays, the theoretical risks from ESD therefore appear low.

In addition, CEN/TC 205/WG 14 is unaware of actual reports of patient safety related incidents from ESD, and in the absence of such evidence believes there is no requirement to include ESD testing for clean air suits in this document.

CEN/TC 205/WG 14 notes that there are user comfort issues associated with static charge and ESD, and manufacturers can wish to take this into account when selecting materials and designing devices.



**Annex C**  
(informative)  
**Environmental aspects**

This document provides test methods and performance requirements for the characteristics of clean air suits which enable assessment of compliance with the relevant essential requirements of Annex I of Directive 93/42/EEC on Medical Devices.

In order to reflect the broad variety of technologies currently used to manufacture and (if applicable) process surgical textiles and not to hinder technical development and innovation, the requirements set by this document are expressed in terms of quantifiable performance rather than specific technical design or descriptive characteristics.

This document does not specify any technical solution to meet the requirements set in this document and hence does not include any technical provisions for manufacturing and processing and their respective environmental impacts. As this document does not include environmental provisions, this document does not provide an environmental checklist.



## Annex D (informative) Guidance to users for selecting products

### D.1 General

The selection and use of clean air suits for specific surgical procedures should be covered by risk assessment and quality management and can be subject to local, regional or national infection prevention regime, guidelines, directives or regulations.

### D.2 Performance levels

This document introduces two performance levels ('standard performance' and 'high performance') for clean air suits, thereby acknowledging the fact that different products may be required depending on the microbial cleanliness of the operating room required for the procedure. The differentiation of 'standard performance' from 'high performance' products is based on the barrier performance of the products. For infection-prone clean surgery, air counts in the operation room of less than 10 CFU/m<sup>3</sup> are recommended [15]. To achieve that level, standard performance clean air suits can be used in operating rooms with high air flow rates, but in operating rooms with average ventilation, e.g. 0,56 m<sup>3</sup>/s (equalling 17 air changes/h in an average operating room) [32], high performance clean air suits are needed, particularly when the operation requires a high number of persons present.

**NOTE 1** For details of the differences in the required barrier performance, see Table 1.

By establishing two performance classes, this document facilitates the assessment of the barrier performance of products. This document does not include specific recommendations for selecting clean air suits with regard to the type of surgical procedure the product is to be used with.

The user should select clean air suits based on their performance levels in order to meet the anticipated challenges of the surgical procedure (e.g. in terms of duration, mechanical stress and temperature) and the microbial cleanliness of the operating room required for the procedure.

**NOTE 2** In clean-room clothing systems, not primarily intended for operating room use, the suit has long sleeves, is designed as a coverall, and is worn with a hood and textile boots. Such clothing systems have practical drawbacks, such as difficulty in performing hand disinfection. In addition, garments made from tight materials can impair the comfort of the wearer, particularly when performing physically heavy and stressful work such as large surgical procedures. When a high performance clean air suit is required, e.g. in operating rooms with a low airflow where the clinician considers the patient to be particularly infection-prone, a complete clean-room clothing system can be considered.

### D.3 Functional design aspects

#### D.3.1 Size

This document does not include provisions for specifying the size of products in a standardized way.

Products should have suitable size and construction to fulfil the intended use of the clean air suit, and to ensure safety and freedom of movements. Selecting products of suitable size to appropriately cover persons is up to the user.



### **D.3.2 Accessories**

This document does not include specific provisions for accessories like e.g. cuffs or buttons.

Therefore, accessories need not to meet any requirements of this document, and the user should assess the functional design with consideration to the placement of accessories so that the intended uses of the products are not compromised. The user should also assess the quality of any accessories in order to ensure that the intended uses of the products are not compromised.

## **D.4 Comfort**

### **D.4.1 General**

The concept of comfort is based on several different factors, such as physiological comfort, ease of movement or factors that will influence and/or affect the individual's work performance and satisfaction with the product. Garments made from tight materials can impair the comfort of the wearer, particularly when performing physically heavy and stressful work such as large surgical procedures.

The comfort of a product depends on such properties as its thermal resistance, air permeability, watervapour resistance, drapeability, tactile comfort and other properties like stretchability, weight, size, fit, fibres and manufacture.

**NOTE 1** Drapeability addresses the ability of a material to conform to a given shape or object.

**NOTE 2** Water-vapour resistance is defined as the water-vapour pressure difference between the two faces of a material divided by the resultant evaporative heat flux per unit area in the direction of the gradient. The evaporative heat flux can consist of both diffusive and convective components. EN 31092 provides a test method for measuring the thermal and water-vapour resistance under steady-state conditions.

**NOTE 3** Thermal resistance is a property of a material that can be measured by a thermal manikin in view to determine important parameters relevant to clothing thermal comfort.

**NOTE 4** Tactile comfort also indicated as softness, is highly dependent on the fibre smoothness and the finish technologies.

**NOTE 5** Properties such as stretchability, size fit, weight, can be measured.

Discomfort properties, such as rustling tendency, softness and skin irritation are difficult to measure.

Evaluation should be based on trials of the products or practical experience.

The user when selecting products for use should assess the comfort of products in order to exclude any significant limitations of the intended use of the product. Combinations of materials and design of clothing systems (including technical underwear or garments) that will minimize the physiological stress during work are to be encouraged.

### **D.4.2 Clean air suits**

The overall comfort of clean air suits can be influenced by a number of factors mentioned in D.4.1. Other important variables that can influence comfort include undergarments, health and physical conditions, workload, mental stress and environmental conditions, such as temperature, relative humidity, and air changes in operating room.



The perception of comfort is subjective and can be influenced by one or a combination of the aforementioned factors.

#### **D.4.3 Practical trials**

Not all the necessary properties of a product can be tested according to this document. The products should be tested practically in clinical situations where the end-user is going to apply them, to ensure that they are suitable from all important aspects including functionality and comfort. The practical trials should be evaluated before selection of products.



## Annex E (Informative) Functional design

### E.1 General

The literature shows that the main dispersal of bacteria-carrying particles is derived from the lower part of the trunk, and that males disperse more such particles than females [27]. Skin scales carrying microorganisms have an average equivalent particle size of approximately 10  $\mu\text{m}$  to 12  $\mu\text{m}$ . Skin scales are fragmented into smaller particles when passing through clothing materials. These particles are dispersed from the body with movements, and with convection by body heat. When the material of the worn garment is tight, as required for the clean air suit in this document, bacteria are dispersed through the openings for head, arms and feet [29]. Arm and feet openings shall therefore be closed by cuffs or other similar solutions that will grant a good seal. A barrier hood should be worn, tucked into the gap at the neckline. If the suit consists of blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting cuff at the waist.

A standard performance clean air suit should be designed as above, and made from material that fulfils the requirements given in Table 1.

A high performance clean air suit should be designed as above and made from material that fulfils the requirements given in Table 1.

**NOTE** In clean-room clothing systems, not primarily intended for operating room use, the suit has long sleeves, is designed as a coverall, and is worn with a hood and textile boots.

To test the design and material of a clean air suit, dispersal experiments can be performed. The clean air suit is intended to reduce the dispersal of bacteria-carrying particles to acceptable levels, measured as source strength, in an environment with defined ventilation. The tests can be performed in a dispersal chamber or in operating rooms during clinical or simulated standardized surgical procedures (see below). The dispersal chamber test is not sensitive enough to evaluate minor changes in design and accessories, such as wearing a face mask or not, but could show the importance of quality and design of head coverings.

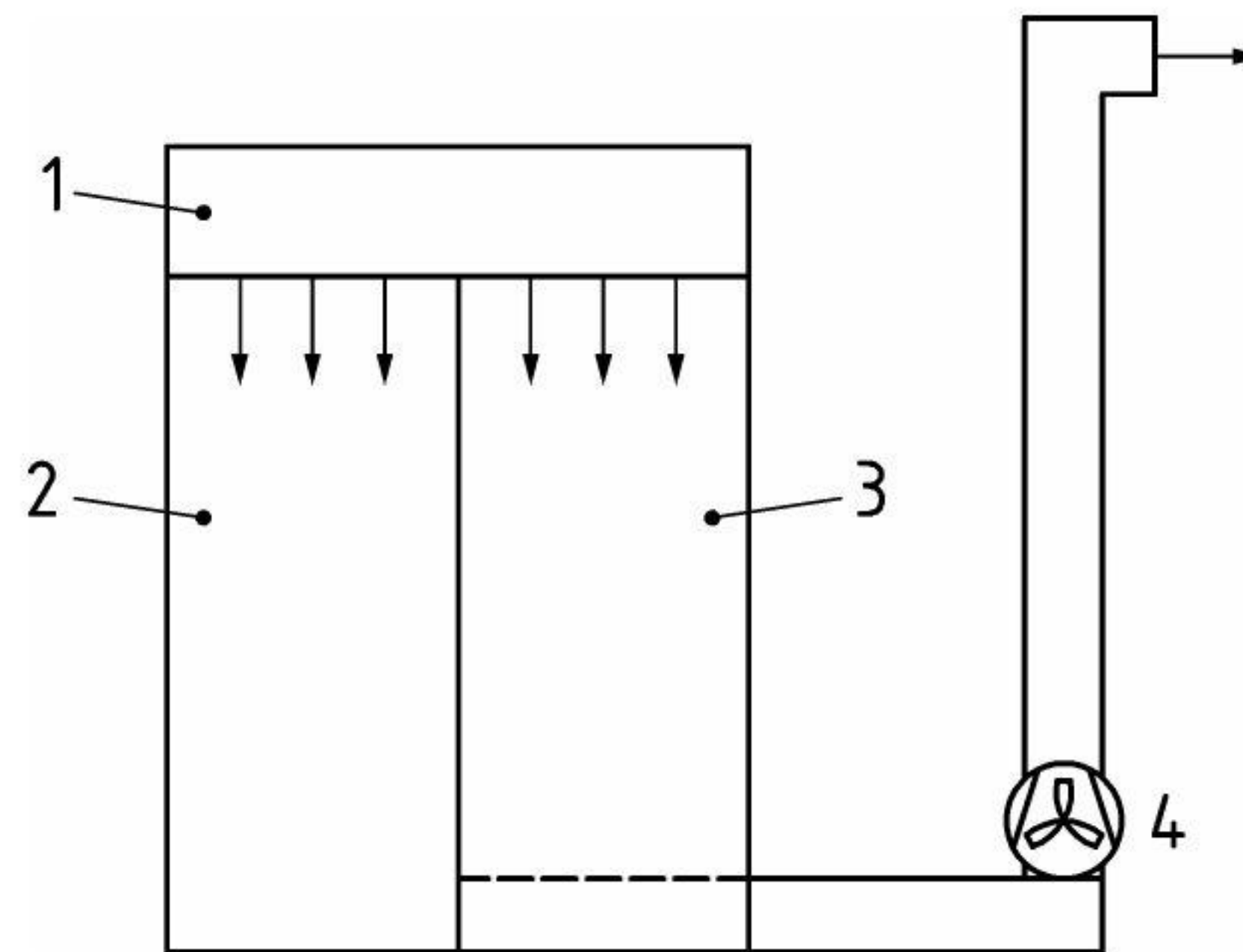
When comparing designs, they should be made of the same material. When correlating dry penetration and particle penetration of a material to source strength in the dispersal chamber, the same design should be tested, in the correct sizes for the test persons.

### E.2 Test method for measuring source strength

#### E.2.1 Dispersal chamber

A dispersal chamber (or "body box") is a qualified/validated chamber with a volume of approximately 2  $\text{m}^3$ , with tightly sealed walls and door, and with a specified inflow of HEPA-filtered air at positive pressure ( $\approx 10$  Pa) and controlled outflow (see Figure E.1). A description of a dispersal chamber is given in [30].





### Key

- 1 HEPA filter
- 2 changing area
- 3 body box
- 4 exhaust fan

**Figure E.1 — Dispersal chamber (adapted from [30])**

The test person is male, 20 years to 50 years old, with no visible skin disorder.

The test person performs a test cycle consisting of a standardized series of movements during 10 min [30].

### E.2.2 Operating room

Practical tests of the clean air suit can also be performed in an operating room with a known number of people and known air flow. The source strength per person will then be about half of that measured in a test chamber.

Measurements in an operating room with a known air flow rate should be performed in 10 hip replacement procedures with 5 to 10 persons present, all wearing the same type of clean air suit. During each procedure,  $\geq 5$  active air samplings, each sampling 0,5 m<sup>3</sup> to 1 m<sup>3</sup> of air, should be performed. Measurement shall be performed after incision and before the closure of the wound. The test results are reported as source strength per person (mean/median and min-max values). The hip replacement procedures can be clinical or simulated [31].

### E.2.3 Measuring bacteria carrying airborne particles

Active air sampling 0,05 m<sup>3</sup>/min to 0,1 m<sup>3</sup>/min, with 50 % deposition for equivalent aerodynamic particle size  $\leq 2 \mu\text{m}$ . Details of sampling techniques are given in [32].

### E.2.4 Source strength

The source strength is defined as the number of bacteria carrying particles (CFU) emitted per second from a person wearing a specified garment. The source strength depends on the design of a garment, and of the material used, but also on the wearer and the type of activity performed. The measurements can be performed in a dispersal chamber (see above) and in simulated or in clinical surgical procedures.



### E.3 Use of source strength measurements

The source strength is an approximation based on 20 measurements in a dispersal chamber, with five male test persons, each performing a standardized exercise four times on separate days. It enables classification of the products into broad groups but with a grey zone between them. Measurement in operating rooms can be used for clinical assessment of the products to see whether the product in a given environment gives the desired microbial air cleanliness (see Figure E.2) [32].

In most operating rooms, the ventilation is turbulent due to the inflow and the presence of heating devices (lamps and other equipment, people). The following equation can be used to decide which type of clothing is needed in a room with a given airflow rate and a given number of people [32].

$$Q = (n \times q_s) / c \quad [E.1]$$

where

$c$  = concentration measured in CFU/m<sup>3</sup>;  
 $Q$  = airflow measured in m<sup>3</sup>/s;  
 $q_s$  = source strength calculated in CFU/s;  
 $n$  = number of people.

To determine the source strength of a known number of people wearing one type of clothing in a room with known ventilation, the equation would be written as

$$q_s = (c \times Q) / n \quad [E.2]$$

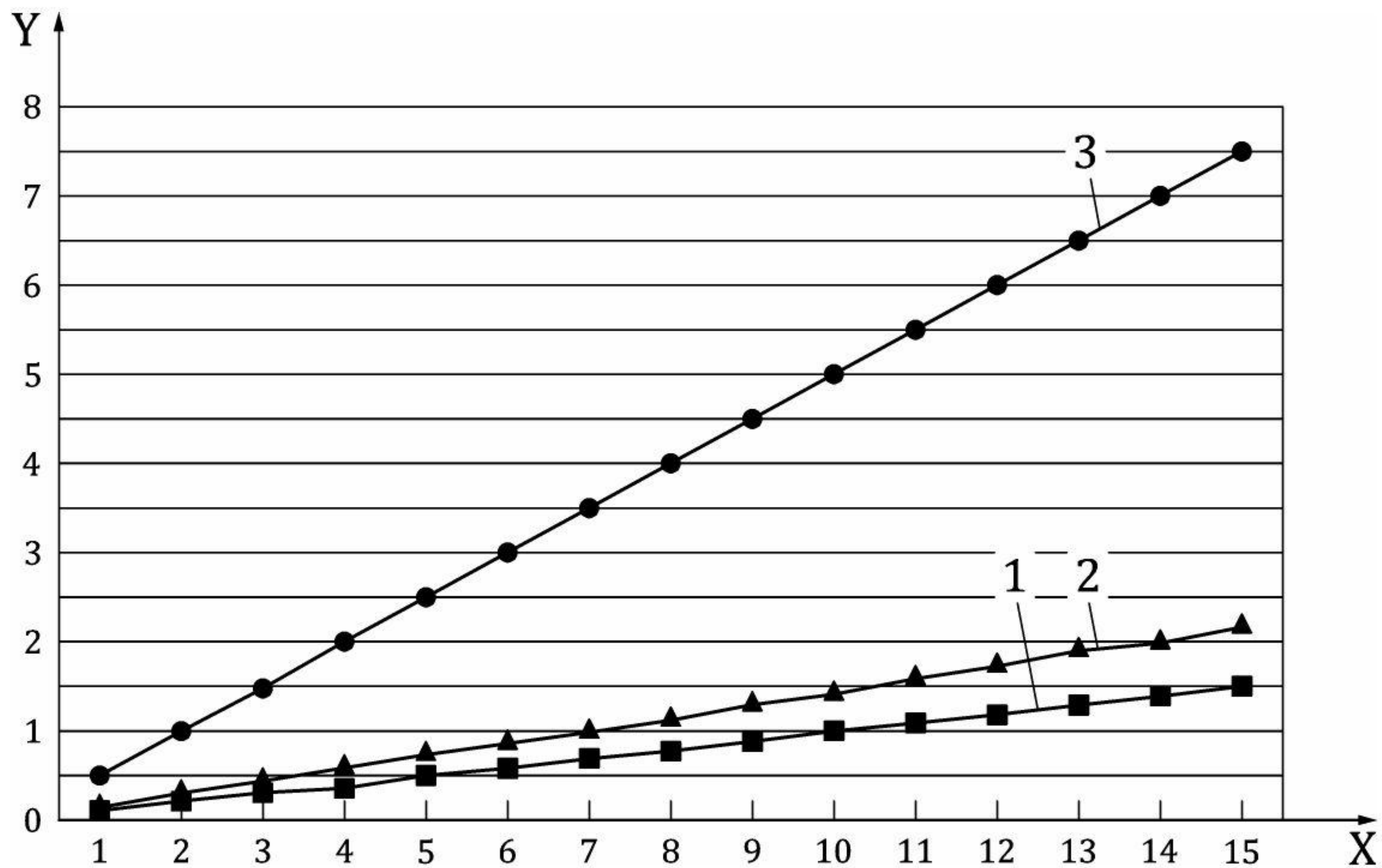
The ventilation can be measured as air changes/h or as m<sup>3</sup>/s. A room with floor area 30 m<sup>2</sup>, height 3,5 m, i.e. volume 105 m<sup>3</sup>, and 19 air changes/h which has been a common design, would then be ventilated with 2 000 m<sup>3</sup>/h or 0,56 m<sup>3</sup>/s.

The steady-state CFU/m<sup>3</sup> ( $c$ ) depends on the number of persons present ( $n$ ), the bacteria-carrying particles dispersed from them, source strength ( $ss$ ), CFU/s ( $q_s$ ) and the clean air flow to the operating theatre m<sup>3</sup>/s ( $Q$ ). It is independent of the size of the room and is calculated as follows:

$$c = (n \times q_s) / Q \quad [E.3]$$

Air counts of 10 CFU/m<sup>3</sup> or less are required during surgical procedures for clean infection-prone operations. The equation can be used to predict which air flow rates and type of clothing that are needed for this level of air cleanliness. Figure E.2 shows some examples.





#### Key

- 1 source strength 1 CFU/s
- 2 source strength 1,5 CFU/s
- 3 source strength 5 CFU/s
- X number of people in the room
- Y air flow m<sup>3</sup>/s

**Figure E.2 — Graphical representation of source strength needed to achieve 10 CFU/m<sup>3</sup> in operating rooms with different air flows and numbers of people**

Standard clean air suits give a source strength of 2,5 CFU/s to 3,5 CFU/s in the dispersal chamber and 1 CFU/s to 2 CFU/s in the operating room. High-performance clean air suit give a source strength of 0,5 CFU/s to 1,5 CFU/s in the dispersal chamber and < 1 CFU/s in the operating room. The rationale for the difference in source strength of the same garment between the chamber and the room is that movements in the chamber are more vigorous than in the room; also, test persons in the operating room are mostly female and therefore disperse fewer skin microorganisms than the male persons in the chamber [34]. Further studies are needed to establish the relationship between dry penetration and source strength [35].

For further information, see Bibliography [36], [37], [38] and [39].



## Annex ZA (informative)

### Relationship between this European standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request 'M/295 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993 OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

**NOTE 1** Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

**NOTE 2** The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

**NOTE 3** When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this standard

**Table ZA.1 — Correspondence between this European standard and Annex I of  
Directive 93/42/EEC [OJ L 169]**

Essential Requirement of Directive 93/42/EEC	Clause(s) subclause(s) of this EN	Remarks/Notes
8.1, first sentences only	4, A.2.1, A.2.5	Covered for cleanliness(bioburden) and dry microbial penetration
9.2, second indent only	4, A.2.3 and A.2.4	Covered for bursting strenght(dry) and tensile strenght (dry)
13.6 h), first paragraph only	6.2	Covered for the number of reuses

**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2** — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.



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- [3] EN 62366, *Medical devices — Application of usability engineering to medical devices*
- [4] EN ISO 9237, *Textiles - Determination of permeability of fabrics to air (ISO 9237)*
- [5] EN ISO 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5)*
- [6] EN ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10)*
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## Informasi pendukung terkait perumus standar

### [1] Komite Teknis

Komite Teknis 13-09 Biosafety and Biosecurity

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